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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

THE ESTATE OF MARY PROCOPIO and CHRISTINE LANG, EXECUTOR OF THE ESTATE OF MARY PROCOPIO, DECEASED, INDIVIDUALLY, *Plaintiffs,* *v.* **ACTAVIS GROUP hf,** **ACTAVIS GROUP PTC, ehf,** **ACTAVIS TOTOWA, LLC (formerly known as Amide Pharmaceutical, Inc.),** **ACTAVIS INC.,** **ACTAVIS ELIZABETH, LLC,** **ACTAVIS US,** **MYLAN, INC.,** **MYLAN PHARMACEUTICALS, INC.,** **MYLAN LABORATORIES, INC.,** **MYLAN BERTEK PHARMACEUTICALS INC.,** *and,* **UDL LABORATORIES, INC.,** *Defendants.*	**CIVIL ACTION** **CASE NUMBER** **COMPLAINT AND DEMAND FOR JURY TRIAL** **JURY TRIAL DEMANDED**

COMPLAINT

I. INTRODUCTION

Plaintiffs, the Estate of Mary Procopio ("Decedent") and Christine Lang Individually and as Executor of the Estate of Mary Procopio, (collectively "Plaintiff or Plaintiffs") alleges as

follows:

1. Plaintiffs brings this action against the Defendants for design, manufacturing, producing, supplying, inadequately inspecting, testing, selling and distributing dangerous, defective, misbranded and adulterated Digitek® (digoxin tablets, USP)(hereinafter referred to as "Digitek") containing an amount of the drug's active ingredient, digoxin, different from the dose set forth on the label and in some cases exceeding the dose approved for medical treatment in humans. By reason of the wrongful conduct of the Defendants, and the dangers posed by the potential for overdoses of the drug, a massive, national recall of Digitek® tablets has been initiated in the United States.

2. Upon information and belief, the recall implicated Digitek® tablets manufactured in a plant in Little Falls, New Jersey as early as 2006. Notably, on August 1, 2008, the Actavis Defendants announced a retail-level recall of all drugs manufactured at its Little Falls, New Jersey Plant.

3. The expanded recall was prompted by yet another inspection at the facility which revealed that operations still did not meet the FDA's standards for good manufacturing practices. This recall implicated 65 different generic drugs all manufactured at the same facility that produced Digitek® tablets.

4. Since the August, 2008 recall, Defendant Actavis finally closed the New Jersey plants to institute "remediation" efforts. However, it sought to reopen the facilities, prompting the United States Justice Department to file a lawsuit in November, 2008 to force closure.

5. Under a Consent Decree reached in December, 2008, the Actavis Defendants agreed to not distribute any products from the closed facilities until it has certified completion of

certain enumerated requirements that demonstrate compliance with FDA's current good manufacturing practice and has passed follow-up FDA inspections of the facilities.

6. The Actavis plant in Little Falls, New Jersey remained closed until approximately April 17, 2009, according to an Actavis Press release which stated that the FDA completed its inspection of Little Falls and approved the release of the first two products as outlined in the Decree: Oxycodone 15 mg and 30 mg tablets upon information and belief manufacture of Digitek has still not resumed as of this date.

II. STATEMENT OF JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §1332 (Diversity) in that the state of citizenship of the Plaintiff is different from the state of citizenship of the Defendants, and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

8. Plaintiff alleges an amount in controversy in excess of $75,000.00 exclusive of interest and costs, as to themselves and each member of the proposed Class.

9. Venue is proper pursuant to 28 U.S.C. § 1391. The Defendants have sufficient minimum contacts with New Jersey or otherwise intentionally avails itself of the consumer markets within New Jersey through the promotion, sale, marketing and/or distribution of its products in the state to render the exercise of jurisdiction by the New Jersey courts permissible under traditional notions of fair play and substantial justice.

III. PARTIES

A. PARTY PLAINTIFFS

10. Plaintiff, Christine Lang, is the daughter of Decedent, Mary Procopio, and is the Executor of her Estate duly appointed by Letters Testamentary entered on September 21, 2009 in

Commonwealth of Pennsylvania, Allegheny County Orphans' Court Division. Plaintiff Christine Lang is also an individual residing at 533 Fieldcrest Drive, Pittsburgh, PA 15209.

11. The Decedent, Mary Procopio, was at all relevant times resident of the Commonwealth of Pennsylvania.

12. The Decedent, ingested Digitek® pursuant to a physician's prescription and suffered serious personal injuries including digoxin toxicity and wrongful death on or about February 7, 2008 as a result of her ingestion of said Digitek®.

B. THE "ACTAVIS DEFENDANTS"

13. Defendant Actavis Group hf is an international generic pharmaceutical company, with its principal place of business at Dalshraun 1 220 Hafnarfjodur, Iceland, and regularly conducts business throughout the United States and specifically in New Jersey, including but not limited to directing the operation and management of the other "Actavis Defendants," including Defendant Actavis Group PTC, ehf, which is the parent of Defendants Actavis, Inc., Actavis Totowa, LLC (formerly known as Amide Pharmaceutical, Inc.), Actavis Elizabeth, LLC, and Actavis, US, in the design, development, manufacture, production, processing, compounding, formulating, testing, sale, marketing, labeling, packaging, dosing advertising, promotion, supply, releasing and/or distribution of Digitek®.

14. Defendant Actavis Totowa, LLC (formerly known as Amide Pharmaceutical, Inc.) is a corporation organized and existing under the laws of Delaware with its principal place of business in New Jersey, at 101 East Main Street, Little Falls, NJ 07424-5608 and is a wholly-owned subsidiary, agent, and alter ego of Actavis Group hf.

15. Defendant Actavis Elizabeth, LLC is a corporation organized and existing under

the laws of Delaware with its principal place of business in New Jersey 200 Elmora Ave Elizabeth, NJ 07202 and is a wholly-owned subsidiary, agent, and alter ego of Actavis Group hf.

16. Defendant Actavis, Inc. is a corporation organized and existing under the laws of Delaware with its principal place of business New Jersey, at 14 Commerce Drive, Suite 301,Cranford, NJ and is a wholly-owned subsidiary, agent, and alter ego of Actavis Group hf.

17. Defendant Actavis, US is a corporation organized and existing under the laws of Delaware with its principal place of business in New Jersey, at 60 Columbia Rd Bldg B, Morristown, NJ 07960-4535 and is a wholly-owned subsidiary, agent, and alter ego of Actavis Group hf.

18. Defendants Actavis Group hf., Actavis Totowa (formerly known as Amide Pharmaceutical, Inc.) Actavis Inc., Actavis Elizabeth, LLC and Actavis U.S. are referred to hereinafter collectively as "Actavis" or "Actavis" Defendants" unless otherwise stated.

19. At material times hereto, the Actavis Defendants:

a. were, and are, engaged in the business of the design, development, manufacture, production, processing, compounding, formulating, testing, sale, marketing, labeling, packaging, dosing advertising, promotion, supply, releasing and/or distribution of Digitek®. in the United States and New Jersey either directly or indirectly through third-parties or related entities;

b. were, and are, in the business of profiting from the in the design, development, manufacture, production, processing, compounding, formulating, testing, sale, marketing, labeling, packaging, dosing advertising, promotion, supply, releasing and/or distribution of Digitek®;

c. conducted continuous and substantial business in the state of New Jersey and,

d. acted and gained knowledge itself and by and through its various agents, servants, employees, and/or ostensible agents.

B. THE "MYLAN DEFENDANTS"

20. Defendant Mylan, Inc. is a corporation organized and existing under the laws of Pennsylvania with its principal place of business in New Jersey a 530 Main Street, Chester, NJ 07930 .

21. Defendant Mylan Laboratories, Inc. ("Mylan Laboratories") is a corporation organized and existing under the laws of Pennsylvania with its principal place of business in New Jersey at One Woodbridge Center, 9th Floor, Suite 920, Woodbridge, NJ 07095.

22. Defendant Mylan Pharmaceuticals, Inc. ("Mylan Pharmaceuticals") is a corporation organized and existing under the laws of West Virginia with its principal place of in New Jersey at 1405/1425 Route 206 South Bedminster, NJ 07921 and is a wholly-owned subsidiary, agent, and alter ego of Defendant Mylan, Inc.

23. Defendant Mylan Bertek Pharmaceuticals, Inc. ("Mylan Bertek") is a corporation organized and existing under the laws of Texas with its principal place of business at 12720 Dairy Ashford Rd Sugar Land, TX 7747 and is a wholly-owned subsidiary, agent, and alter ego of Defendant Mylan, Inc.

24. Defendant UDL Laboratories, Inc. ("UDL") is a corporation organized and existing under the laws of West Virginia with its principal place of business in Illinois at 1718 Northrock Court, Rockford, IL 61103 and is a wholly-owned subsidiary, agent, and alter ego of Defendant Mylan, Inc.

25. Defendants Mylan Inc., Mylan Laboratories, Mylan Pharmaceuticals, Mylan Bertek and UDL are referred to hereinafter collectively as "Mylan" or the "Mylan Defendants," unless otherwise stated.

26. At material times hereto, the Mylan Defendants:

a. were, and are, engaged in the business of the design, development, manufacture, production, processing, compounding, formulating, testing, sale, marketing, labeling, packaging, dosing advertising, promotion, supply, releasing and/or distribution of Digitek®. in the United States and New Jersey either directly or indirectly through third-parties or related entities;

b. were, and are, in the business of profiting from the design, development, manufacture, production, processing, compounding, formulating, testing, sale, marketing, labeling, packaging, dosing advertising, promotion, supply, releasing and/or distribution of Digitek®.;

c. conducted continuous and substantial business in the state of New Jersey and,

d. acted and gained knowledge itself and by and through its various agents, servants, employees, and/or ostensible agents.

IV. FACTUAL ALLEGATIONS

The Drug - Digitek® (digoxin tablets, USP)

27. Digitek® is the brand-name of one of the cardiac glycosides, a closely related group of drugs having in common specific effects on the myocardium of the heart.

28. Digitek® is a registered trademark of Defendant Bertek Pharmaceuticals.

29. Digitek® is widely prescribed and used by millions of Americans to treat various

heart conditions, including atrial fibrillation, atrial flutter and congestive heart failure.

30. Digitek® and digoxin are metabolized in the liver but excreted by the kidney.

31. Digitek® is approved only for sale and distribution in the United States in the following dosages:

Digitek® (digoxin tablets, USP) 0.125 mg, and,

Digitek® (digoxin tablets, USP) 0.250 mg

(collectively referred to hereinafter as the "approved dose").

32. Each Digitek® tablet is approved by the United States Food and Drug Administration ("FDA") only for sale and distribution if it contains the labeled amount of digoxin.

33. Digitek® tablets manufactured and produced with an amount of digoxin in less than or excess of the labeled dose are not approved for sale or distribution in the United States (hereinafter "unapproved excessive dose").

THE FDA WARNING LETTERS

The August 15, 2006 FDA Warning Letter

34. Upon information and belief, some of the Recalled Digitek® was designed, developed, manufactured, produced, processed, compounded, formulated, tested, sold, marketed, labeled, packaged, dosed, advertised, promoted, supplied, released and/or distributed from a plant in Little Falls, New Jersey owned by one or more of the Actavis Defendants, which was acquired in December 2005 as part of Actavis' acquisition of another company's generic business.

35. On or about August 15, 2006, the FDA issued a letter warning to the Actavis Defendants through defendant Actavis Totowa for failing to file periodic safety reports at its

solid oral dose manufacturing facility in Little Falls, New Jersey (hereinafter referred to as the "*August, 2006 Warning Letter*").

36. The *August, 2006 Warning Letter* is available on the FDA's website at http://www.fda.gov/foi/warning_letters/archive/g6235d.htm.

37. In the *August, 2006 Warning Letter*, the FDA warned the Actavis Defendants through Actavis Totowa that it had violated its adverse medical event reporting obligations, marketing drugs without proper clearance and causing at least 26 adverse drug experiences (ADEs) by not submitting periodic safety reports.

38. According to the FDA's *August 2006 Warning letter*, an FDA inspection between January and February 2006 revealed that there were six potentially serious and unexpected adverse drug events dating back to 1999 for products, including digoxin, that were not reported to the agency.

39. The FDA's *August 2006 Warning letter* also warned the Actavis Defendants through Actavis Totowa about not properly investigating serious and unexpected ADEs, not adequately reviewing ADE information, failing to file periodic safety reports which resulted in at least 26 ADEs which were never reported.

40. The FDA's *August 2006 Warning letter* also warned the Actavis Defendants through Actavis Totowa that it had not developed procedures for the surveillance, receipt, evaluation, and report of adverse events.

The Revised Warning Letter About the Actavis Defendants' "Significant Deviations from the Current Good Manufacturing Practice Regulations"

41. In or around February 1, 2007, the FDA issued a revised Warning Letter to the Actavis Defendants through Actavis Totowa (hereinafter "*Revised Warning Letter*") citing "significant deviations from the current Good Manufacturing Practice regulations."

42. The *Revised Warning letter* is available on the FDA's website at http://www.fda.gov/ foi/warning_letters/archive/g6235d.htm.

43. In the *Revised Warning letter* the FDA noted several deviations from good manufacturing process, resulting in the adulteration of drug products manufactured by the Actavis Defendants, that were observed by the FDA during an inspection conducted July 10, 2006 to August 10, 2006.

44. According the FDA's *Revised Warning Letter*:

> Significant deficiencies were found in the operations of your firm's quality control unit, and as a result there is no assurance that many drug products manufactured and released into interstate commerce by your firm have the identity, strength, quality and purity that they purport to possess.

45. The deviation from good manufacturing process observed by the FDA were presented to Actavis Totowa on an FDA-483 (List of Inspections) at the close of the inspection on August 10, 2006.

46. The FDA's *Revised Warning letter* cited deficiencies in the operations of the Actavis Defendants' quality control unit, which included instances where the unit failed to adequately investigate and resolve laboratory deviations and out-of-specification test results for drug products. Specifically, according to the *Revised Warning letter*:

> Our investigators observed numerous instances where the quality control unit failed to adequately investigate and resolve laboratory deviations and out-of-specification test results involving drug products that ultimately were released for distribution into interstate commerce. Additionally, our investigators uncovered out-of-specification test results in laboratory raw data that were not documented in laboratory notebooks, and found that products were released based on retesting without any justification for discarding the initial out-of-specification test results.

47. The FDA *Revised Warning letter* stated that the FDA found during its inspection

that analysts did not always document the preparation and testing of samples at the time they were done:

> Master and batch production and control records were found to be deficient in that they did not include complete procedures for documenting the collection of samples. Although your firm's procedures require the collection of in-process blend uniformity samples of three times the weight of finished product tablets or capsules, master production records do not require, and batch records do not contain, documentation that the samples are being collected accordingly. [21 CFR 211.186(b)(9) and 21 CFR 211.188(b)(10)]

48. The FDA also cited a failure to check for accuracy the input and outputs from a system used to run the high-performance liquid chromatography during analysis of drug products.

49. Among other deficiencies cited by the FDA in the *Revised Warning letter* were: Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

a. failure of the quality control unit to recognize that some tablets did not meet in-process specifications;

b. a lack of adequate procedures for conducting bulk product holding time studies; failure to identify and control rejected in-process materials;

c. not adequately qualifying select equipment; and,

d. failure to establish and follow written procedures for maintaining manufacturing equipment.

50. By way of example, the FDA states in the *Revised Warning Letter* that:

> Your firm's cleaning validation studies were found to be inadequate and, as a result, there was no assurance that equipment is adequately cleaned between the manufacture of different drug products. [21 CFR 211.67(b)] For example:
>
> a) Cleaning validation was performed for the process trains without

evaluating for sample recovery for numerous products, including: Amidal Nasal Decongestant; Amigesic Caplets, 750mg; Carisoprodol and Aspirin Tablets, USP, 200mg/325mg; Carisoprodol Tablets, USP, 350mg; Chlorzoxazone Tablets, USP, 250mg and 500mg; Digoxin Tablets, USP, 0.25mg.

51. The FDA gave the Actavis Defendants through Actavis Totowa 15 working days to provide a written listing of all released lots of finished drug products that remain within specification that are associated with any out-of specification test results during manufacture and to provide description of the actions taken to ensure that lots were suitable for release.

The Manufacture, Production, Labeling, Distribution and Sale of Dangerous Digitek® Tablets Containing an Amount of Digoxin, Less than or Exceeding the Labeled Dose Including Some With A Dose Exceeding that Approved for Medical Treatment in Humans

52. The Defendants are drug companies, that upon information and belief, engaged in the design, development, manufacture, production, processing, compounding, formulating, testing, sale, marketing, labeling, packaging, dosing, advertising, promotion, supply, releasing and/or distribution of Digitek® tablets containing an amount of digoxin, different than the dose on the label.

53. At all times relevant to this action, Defendants knew, and/or had reason to know, that the Recalled Digitek® was not safe for the patients for whom the drug was prescribed because it either contained an less than or an excess dose of digoxin which can cause serious medical problems, digoxin overdose, digitalis toxicity and, in certain patients, catastrophic injuries and death.

The Class I-Recall in the United States And Defendants' Failure to Provide Full, Complete and Adequate Information About the Recalled Digitek®

54. On or about April 25, 2008, the United States Food and Drug Administration ("FDA") announced a Class I Recall of all lots of Bertek and UDL Laboratories Digitek® (hereinafter "Recalled Digitek®"). The FDA announcement, available at http://www.fda.gov/

medwatch/safety/2008/safety08.htm#Digitek, stated:

> DIGITEK (DIGOXIN TABLETS, USP)
> Audience: Cardiologists, family physicians, pharmacists, other healthcare professionals, patients
> [Posted 04/28/2008] Actavis Totowa LLC notified healthcare professionals of a Class I nationwide recall of all strengths of Digitek, a drug used to treat heart failure and abnormal heart rhythms. The products are distributed by Mylan Pharmaceuticals Inc., under a "Bertek" label and by UDL Laboratories, Inc. under a "UDL" label. The product is being recalled due to the possibility that tablets with double the appropriate thickness may contain twice the approved level of active ingredient. The existence of double strength tablets poses a risk of digitalis toxicity in patents with renal failure. Digitalis toxicity can cause nausea, vomiting, dizziness, low blood pressure, cardiac instability and bradycardia. Several reports of illnesses and injuries have been reported. Patients should contact their healthcare professional with questions.
> [April 25, 2008 - Press Release - Actavis Totowa LLC]

55. Class I Recalls are instituted only when there exists a reasonable probability that use of the product will cause serious injury or death.

56. The Recalled Digitek® is an adulterated drug and its label and packaging are misbranded.

Injuries from Digoxin Overdose, Digitalis Toxicity or from An Amount of Digoxin Less than the Labeled Dose

57. Digoxin overdose and digitalis toxicity can cause serious and life-threatening personal injury, and death.

58. The Digitek® label states, in relevant parts, under "Precautions" that:

Use in Patients with Impaired Renal Function: Digoxin is primarily excreted by the kidneys; therefore, patients with impaired renal function require smaller than usual maintenance doses of digoxin. Because of the prolonged elimination half-life, a longer period of time is required to achieve an initial or new steady-state serum concentration in patients with renal impairment than in patients with normal renal function. If appropriate care is not taken to reduce the dose of digoxin, such patients are at high risk for toxicity, and toxic effects will last longer in such patients than in patients with normal renal function.

* * *

Adults: *Cardiac*: Therapeutic doses of digoxin may cause heart block in patients with pre-existing sinoatrial or AV conduction disorders; heart block can be avoided by adjusting the dose of digoxin. Prophylactic use of a cardiac pacemaker may be considered if the risk of heart block is considered acceptable. High doses of digoxin may produce a variety of rhythm disturbances, such as first-degree, second-degree (Wenkebach), or third-degree heart block (including asystole); atrial tachycardia with block; AV dissociation; accelerated junctional (nodal) rhythm; unifocal or multiform ventricular premature contractions (especially bigeminy or trigeminy); ventricular tachycardia; and ventricular fibrillation. Digoxin produces PR prolongation and ST segment depression which should not by themselves be considered digoxin toxicity. Cardiac toxicity can also occur at therapeutic doses in patients who have conditions which may alter their sensitivity to digoxin.
Gastrointestinal: Digoxin may cause anorexia, nausea, vomiting and diarrhea. Rarely, the use of digoxin has been associated with abdominal pain, intestinal ischemia and hemorrhagic necrosis of the intestines.
CNS: Digoxin can produce visual disturbances (blurred or yellow vision), headache, weakness, dizziness, apathy, confusion and mental disturbances (such as anxiety, depression, delirium and hallucination).

59. Non-approved, excessive doses of digoxin significantly increase the likelihood that overdosed patients will experience the known side-effects and reactions that can result from the approved doses of digoxin. In other words, the risk and dangers of approved doses are enhanced by an overdose of digoxin.

60. Doses of digoxin less than and exceeding the dose prescribed by a physician for medical treatment can cause personal injury and death.

61. The Digitek® label states in relevant part that:

> Massive Digitalis Overdosage: Manifestations of life-threatening toxicity include ventricular tachycardia or ventricular fibrillation, or progressive bradyarrhythmias, or heart block. The administration of more than 10 mg of digoxin in a previously healthy adult or more than 4 mg in a previously healthy child, or a steady-state serum concentration great than 10ng/mL often results in cardiac arrest.
>
> DIGIBIND [Digoxin Immune Fab (Ovine)] should be used to reverse the toxic effects of ingestion of a massive overdose. The decision to administer DIGIBIND [Digoxin Immune Fab (Ovine)] to a patient who has ingested a massive dose of digoxin but who has not yet manifested life-threatening toxicity should depend on the likelihood that life-threatening toxicity will occur. Patients with massive digitalis ingestion should receive large doses of activated charcoal to prevent absorption and bind digoxin in the gut during enteroenteric recirculation. Emesis or gastric lavage may be indicated especially if ingestion has occurred within 30 minutes of the patient's presentation at the hospital. Emesis should not be induced in patients who are obtunded. If a patient presents more than 2 hours after ingestion or already has toxic manifestations, it may be unsafe to induce vomiting or attempt passage of a gastric tube, because such maneuvers may induce an acute vagal episode that can worsen digitalis-related arrhythmias.
>
> Severe digitalis intoxication can cause a massive shift of potassium from inside to outside the cell, leading to life-threatening hyperkalemia. The administration of potassium supplements in the setting of massive intoxication may be hazardous and should be avoided. Hyperkalemia caused by massive digitalis toxicity is best treated with DIGIBIND [Digoxin Immune Fab (Ovine)]; initial treatment with glucose and insulin may also be required if hyperkalemia itself is acutely life-threatening.

62. The Digitek® label states, in relevant part, under "Adverse Events" that:

> In general, the adverse reactions of digoxin are dose dependent and occur at doses higher than those need to achieve a therapeutic effect. Hence, adverse reactions are less common when digoxin is used within the recommended dose range or therapeutic serum concentration range and when there is careful attention to concurrent medications an conditions.
>
> Because some patients may be particularly susceptible to side effects with digoxin, the dosage of the drug should always be selected carefully and adjusted as the clinical conditions of the patient warrant. In the past, when high doses of digoxin were used and little attention was paid to the clinical status or concurrent medications, adverse reactions were more frequent and severe. Cardiac reactions accounted for about one-half, gastrointestinal disturbances about one-fourth and CNS and other toxicity for about one-fourth of these adverse reactions.

63. The Recalled Digitek® was adulterated, misbranded, defective, unreasonably dangerous and unfit for its intended uses. It contained amounts of Digoxin less than or more than the labeled dose. Defendants placed tens of thousands of patients, including Plaintiff, unnecessarily at risk of serious injury and/or death and may have caused them to suffer personal injuries and harm, including medical expenses, anxiety and fear induced from ingesting the defective and misbranded drug.

64. Defendants knew or should have known about the manufacturing and production defects, misbranding and negligent sale and distribution of the Recalled Digitek® and had a duty to design, develop, manufacture, produce, process, compound, formulate, test, sell, market, label, package, dose, advertise, promote, supply, release and/or distribute only safe Digitek® with approved doses of digoxin and doses of digoxin that were consistent with the dose on the label.

65. Defendants knew or should have known that they designed, developed, manufactured, produced, processed, compounded, formulated, tested, sold, marketed, labeled, packaged, dosed, advertised, promoted, supplied, released and/or distributed Digitek® with too much or too little of the unapproved amounts of digoxin before:

a. any of the Recalled Digitek® was released for distribution and sale; and,

b. they mislabeled the Recalled Digitek®.

66. Defendants failed to implement or utilize adequate safeguards, tests, inspections and quality assurance procedures to ensure the accuracy of the strength of Digitek®.

67. Defendants failed to implement or utilize adequate testing, including batch testing, batch dose verification, and other procedures, safeguards, and inspections to confirm, monitor and assess the quality, dose and safety of Digitek®.

68. Plaintiff was prescribed Digitek® but unwittingly ingested the drug.

69. As a direct and proximate result of the liability-producing conduct of Defendants and the defective and unreasonably dangerous condition of the Recalled Digitek®, the Plaintiffs have suffered physical injury and damage.

70. As a direct and proximate result of the liability-producing conduct of Defendants and the defective and unreasonably dangerous condition of the Recalled Digitek®, the Plaintiffs seek reimbursement of the amounts of money spent for the purchase of the defective, misbranded and adulterated Recalled Digitek®.

71. As a direct and proximate result of the acts and omissions of Defendants, the Plaintiffs suffered serious physical injury, pain and suffering, loss of income, loss of opportunity, loss of family and social relationships, and medical, hospital, surgical and funeral expenses and other expenses related to diagnosis and treatment thereof, for which Defendants are liable

72. As a direct and proximate result of the acts and omissions of Defendants, the Plaintiffs have been prevented from pursuing their normal activities and employment, have experienced severe pain and suffering and mental anguish, and may have been deprived of their ordinary pursuits and enjoyments of life.

73. Plaintiffs incorporate herein any and all factual allegations set forth in the Master Complaint filed in *In re: Digitek Product Liability litigation*, MDL 1968, (S.D. WV).

VI. CLAIMS FOR RELIEF

COUNT 1
PRODUCT LIABILITY – NEGLIGENCE
(N.J.S.A. 2A:58C-1 *et seq.*)

74. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

75. Defendants, directly or indirectly marketed, designed, developed, manufactured, tested, produced, labeled, inspected, packaged, dosed, distributed, promoted, advertised, released, or sold the recalled Digitek® in the stream of commerce in the Commonwealth of Pennsylvania when they knew or in the exercise of ordinary care, should have known that the drug posed a significant risk to the health, well-being and safety of the public and of Plaintiff, which risk was not known to the public, Plaintiff, or their prescribers.

76. At all time material hereto, Defendants had a duty to the Plaintiff to market, design, develop, manufacture, produce, inspect, test, label, package, promote, supply, advertise, distribute and sell Digitek® in a non-defective condition.

77. Defendants negligently, recklessly, grossly negligently, wantonly and willfully breached their duty because, displaying a morally culpable and conscious disregard for the rights of others in that they:

a. failed to market, design, develop, manufacture, produce, test, inspect, label, package, dose, promote, advertise, distribute, release, or sell Digitek® such that it was safe for its intended and foreseeable uses, was not defective and was not unreasonably dangerous;

b. failed to perform proper and sufficient tests to determine the drug's strength/dose;

c. failed to warn at all, or failed to adequately warn foreseeable users such as Plaintiff of the dangers of ingesting recalled Digitek®, and failed to warn of the dose of recalled Digitek®;

d. failed to make reasonable inspections, and/or evaluations necessary to discover such defects and unreasonably dangerous conditions associated with the recalled Digitek®;

e. failed to comply with and/or use reasonable care to comply with standards of good manufacturing, production, inspection and testing practices, care including accepted industry standards, FDA recommendations, government regulations and statutes, in the marketing, design, development, manufacture, testing, inspecting, dosing, labeling and otherwise production, distribution and release of recalled Digitek®;

f. failed to timely remove and/or recall from the market, and/or otherwise prevent the continued contact of Plaintiff with such defects and unreasonably dangerous conditions of recalled Digitek®;

g. failed to investigate and/or use known and/or knowable reasonable

alternative, manufacturing, production, testing and inspection processes for the recalled Digitek®;

h. failed to warn Plaintiff of dangers known and/or reasonably suspected to Defendant to be associated with the recalled Digitek®;

i. failed to make the recalled Digitek® reasonably safe;

j. represented that the recalled Digitek® was reasonably safe for use for its intended purpose, when, in fact, it was not;

k. manufactured the product such that it did nor meet their own specifications and standards, as well as those of the FDA when it approved the drug;

l. failed to timely conduct a recall of the recalled Digitek®, and when the recall was implemented, failed to implement the recall promptly and efficiently and failed to inform the medical community, and the public, including the Plaintiff of all the relevant information such that the significantly increased risk of harm was minimized to the fullest extent possible.

78. Defendants knew or should have known that recalled Digitek® caused unreasonably dangerous risks and side-effects, including death, of which Plaintiff, and Plaintiff's prescribing physicians would not be aware. Defendants nevertheless marketed, advertised, supplied, released, sold and distributed the drug knowing that there were reasonably safer alternative products.

79. The defective design existed before the product left the control of Defendants.

80. The product did not undergo any substantial alteration before reaching Plaintiff.

81. Plaintiff and prescribing physicians were foreseeable users, who were not expected to know of the dangers of recalled Digitek® and who did not know of those dangers.

82. Reasonable consumers would not expect recalled Digitek® to be unreasonably

dangerous.

83. Recalled Digitek's® risks of harm outweigh any potential utility.

84. Reasonably safer alternative products existed and were feasible to use, and they would have prevented or significantly reduced the risk of injury without substantially impairing the product's utility.

85. Recalled Digitek® significantly increases the risk of the known side-effects and reactions that can result from the approved doses of digoxin set forth above.

86. Recalled Digitek® was not approved by the FDA in the form ingested.

87. The above described egregious misconduct constitutes the wanton and willful disregard for health and safety for which punitive damages as well as common law mandate exemplary damages to punish these Defendants and to deter these Defendants from such conduct in the future.

88. As a direct and proximate result of Defendants' negligence and breach of Defendants, Plaintiff had and will continue to have, great physical pain and suffering, and great mental and emotional suffering, some or all of which may be permanent. As a direct and proximate result of the aforesaid, Plaintiff was, and will in the future be, obligated to spend various sums of money to treat, evaluate and care for Plaintiff's injuries; Plaintiff has sustained and will in the future sustain a loss of earnings and earning capacity; Plaintiff's enjoyment of life is impaired; Plaintiff is embarrassed and humiliated; all to Plaintiff's great loss.

89. As a direct and proximate result of Defendants' negligence, Plaintiffs were harmed as aforesaid.

COUNT 2
RES IPSA LOQUITOR

90. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein

91. The design, development, manufacture, production, misbranding, adulteration, distribution, supply, testing, inspection, release or sale of a pharmaceutical with a dose of the drug's active ingredient that was different than the dose on the label and sometimes less than or in excess of the dose approved for human ingestion, *to wit* the Recalled Digitek®, is in and of itself an act that ordinarily bespeaks negligence.

92. During the time when it was being designed, developed, manufactured and produced, the instrumentality, the Recalled Digitek®, was within the Defendants' exclusive control before being released, supplied, distributed or sold to the public including the Plaintiffs.

93. There is no indication in the circumstances set forth herein that the injuries that result from the an overdose or underdose of digoxin, *to wit* the Recalled Digitek®, was the result of Plaintiffs' own voluntary act or neglect.

94. The acts and omissions set forth herein are the type that ordinarily bespeaks negligence and thus liability is established under the doctrine *res ipsa loquitur.*

95. Defendants had a duty to exercise reasonable care in the design, development, testing, manufacture, production, testing, inspection, labeling, packaging, supply, distribution, marketing, promotion, sale and release of the Recalled Digitek®, including a duty to not design, manufacture, produce, label, package, supply, distribute, market, promote, release or sell a pharmaceutical with doses of the drug's active ingredient that were in excess of the dose on the label and sometimes in less than the dose or a dose in excess of the dose approved for human ingestion, *to wit* the Recalled Digitek®.

96. As a direct and proximate result of the acts and omissions of the Defendants as aforesaid, the Plaintiffs were harmed as aforesaid.

COUNT 3
NEGLIGENCE *PER SE*

97. Plaintiffs incorporate by reference each preceding and succeeding paragraph as

though set forth fully at length herein.

98. At all times mentioned herein, Defendants had an obligation not to violate the law, in the design, development, manufacture, production, formulation, compounding, testing, inspecting, processing, assembling, testing, distribution, marketing, labeling, packaging preparation for use, release, sale and warning of the risks and dangers of the aforementioned product.

99. At all times herein mentioned, Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. Section 301, *et seq*., related amendments and codes and federal regulations provided thereunder, and other applicable laws, statutes and regulations.

100. Plaintiffs, as a purchaser and consumer of the Recalled Digitek®, are within the class of persons the statutes and regulations described above are designed to protect, and the injuries alleged herein are the type of harm these statutes are designed to prevent.

101. Defendants' acts constitute an adulteration and misbranding as defined by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 331, and the regulations promulgated therefrom and constitutes a breach of duty subjecting Defendants to civil liability for all damages arising therefrom, under theories of negligence *per se.*

102. Defendants' manufacturing, production, testing and inspection processes are not good manufacturing process Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 331 and the regulations promulgated therefrom and constitutes a breach of duty subjecting Defendants to civil liability for all damages arising therefrom, under theories of negligence *per se.*

103. The acts and omissions set forth herein, demonstrate that Defendants failed to meet the standard of care set by the applicable statutes and regulations, which were intended for the benefit of individuals such as Plaintiffs making Defendants negligent *per se.*

104. As a direct and proximate result of the acts and omissions of the Defendants as

aforesaid, the Plaintiffs were harmed as aforesaid.

COUNT 4
PRODUCT LIABILITY – DEFECTIVE DESIGN
(N.J.S.A. 2A:58C-1 et seq.)

105. Plaintiffs incorporate by reference each preceding and succeeding paragraphs as though set forth fully at length herein:

106. At all times material to this action, the Defendants were responsible for the design, development, manufacturing, production, testing, inspection, packaging, promoting, marketing, distributing, supply, labeling, release and/or sale the Recalled Digitek®.

107. The Recalled Digitek® is defective and unreasonably dangerous to consumers.

108. The Recalled Digitek® is defective in its design or formulation in that it is not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation.

109. At all times material to this action, the Recalled Digitek® was expected to reach, and did reach, consumers in the State of New Jersey and throughout the United States, including the Plaintiffs herein, without substantial change in the condition in which it was sold.

110. At all times material to this action, the Recalled Digitek® was designed, developed, manufactured, produced, tested, packaged, promoted, marketed, distributed, labeled, released and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, the Recalled Digitek® contained an unreasonably dangerous design defect and was not reasonably safe as intended to be used, subjecting the Plaintiffs to risks that exceeded the benefits of the subject product, including but not limited to the risks serious bodily injuries and even death in an unacceptably high number of

its users;

b. When placed in the stream of commerce, the Recalled Digitek® was defective in design and formulation, making the use of the Recalled Digitek® more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with the other digoxin medications and similar drugs on the market, including Digitek® with approved doses of digoxin, with doses that were consistent with the dose on the label;

c. The Recalled Digitek® design defects existed before it left the control of the Defendants;

d. The Recalled Digitek® was insufficiently tested and inspected;

e. The Recalled Digitek® caused harmful side-effects that outweighed any potential utility; and

f. The Recalled Digitek® was not accompanied by adequate instructions and/or warnings and labeling to fully apprise consumers, including the Plaintiffs, of the full nature and extent of the risks and side-effects associated with its use and that it contained an overdose of digoxin, thereby rendering Defendants liable, individually and collectively, to the Plaintiffs.

111. In addition, at the time the subject product left the control of the Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of injury to Plaintiffs without impairing the reasonably anticipated or intended function of the product. These safer alternative designs, including Digitek® with the approved dose of digoxin, consistent with the dose on the label, were economically and technologically feasible, and would have prevented or significantly reduced the risk of injury to Plaintiffs without substantially impairing the product's utility.

112. As a direct and proximate result of the acts and omissions of the Defendants as aforesaid, the Plaintiffs were harmed as aforesaid.

COUNT 5
PRODUCT LIABILITY – MANUFACTURING DEFECT
(N.J.S.A. 2A:58C-1 et seq.)

113. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein:

114. At all times material to this action, Defendants were engaged in the business of designing, developing, manufacturing, producing, testing, packaging, inspecting, promoting, marketing, distributing, supplying, labeling, releasing and/or selling the Recalled Digitek®.

115. At all times material to this action, the Recalled Digitek® was expected to reach, and did reach, consumers in the State of New Jersey and throughout the United States, including the Plaintiffs without substantial change in the condition in which it was sold.

116. At all times material to this action, the Recalled Digitek® was designed, developed, manufactured, produced, tested, packaged, inspected, promoted, marketed, supplied, distributed, labeled, released and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, the Recalled Digitek® contained manufacturing defects which rendered the product unreasonably dangerous;

b. Thes manufacturing defects of the Recalled Digitek® occurred while the product was in the possession and control of the Defendants;

c. The Recalled Digitek® was not made in accordance with the Defendants' specifications or performance standards and/or those specifications and standards approved by the FDA; and,

d. The manufacturing defects of the Recalled Digitek® existed before it left the control of the Defendants;

117. As a direct and proximate result of the acts and omissions of the Defendants as aforesaid, the Plaintiffs and were harmed as aforesaid.

COUNT 6
PRODUCT LIABILITY - FAILURE TO WARN
(N.J.S.A. 2A:58C-1 et seq.)

118. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

119. The Recalled Digitek® was defective and unreasonably dangerous when it left the possession of the Defendants in that it contained labeling, packaging and warnings insufficient to alert consumers, including the Plaintiffs, of the dangerous risks and reactions associated with the Recalled Digitek®, including but not limited, failing to warn that the Recalled Digitek® contained a dose of digoxin inconsistent with the dose on the label and sometimes a dose exceeding the approved dose for use by humans.

120. The Plaintiffs were prescribed and used the subject product for its intended purpose.

121. The Plaintiffs could not have discovered any defect in the subject product through the exercise of reasonable care.

122. The Defendants, as designer, developer, manufacturers, producers, suppliers, inspectors, testers, distributors, releasors or sellers of the subject Recalled Digitek®, a prescription drug, are held to the level of knowledge of an expert in the field.

123. The label, warnings and dosing information that were given by the Defendants with the Recalled Digitek© were not accurate, clear and/or were ambiguous.

124. The label, warnings and dosing information that were given by the Defendants failed to properly warn physicians, the Plaintiffs,and the public that the Recalled Digitek® contained amounts of digoxin different from the dose on the label and sometimes contained a

does not approved for use in humans and thus ingestion risked serious injuries, side effects and/or death.

125. The Plaintiffs, individually and through theirs prescribing physician, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

126. The Defendants had a continuing duty to warn the Plaintiffs of the dangers associated with the Recalled Digitek®.

127. Had the Plaintiffs received adequate warnings or information regarding the dose of digoxin in the Recalled Digitek® and/or information regarding the risks of ingesting the subject product, they would not have used it.

128. As a direct and proximate result of the acts and omissions of the Defendants as aforesaid, the Plaintiffs were harmed as aforesaid.

COUNT 7
STRICT PRODUCTS LIABILITY

129. Plaintiffs incorporate by reference each preceding and succeeding paragraphs as though set forth fully at length herein.

130. At all relevant times, Defendants were the designers, developers, manufacturers, producers, makers, dosers, processors, compounders, forumlaters, labelers, packagers, testers, inspectors, distributor, marketers, promoters, suppliers, releasors and sellers of the Recalled Digitek®, which, at all relevant times, was defective and unreasonably dangerous to consumers.

131. At all relevant times, the Recalled Digitek® was defective in its design, manufacture and production in that it was not reasonably fit, suitable or safe for its intended purpose and/or its foreseeable risks exceed the benefits. The Recalled Digitek® was defective in design, manufacture and production in that it posed a greater likelihood of injury than other properly-dosed digoxin medicines and similar drugs on the market, including properly dosed Digitek® and was more dangerous than ordinary consumers can reasonably foresee.

132. At all relevant times, the defective condition of the Recalled Digitek® rendered it unreasonably dangerous, and the Recalled Digitek® was in this defective condition at the time it left the hands of the Defendants. The Recalled Digitek® was expected to and did reach consumers, including Plaintiffs, without substantial change in the condition in which it was designed, developed, manufactured, labeled, dosed, produced, sold, distributed, marketed, promoted, supplied and otherwise released into the stream of commerce.

133. At all relevant times, Plaintiffs were unaware of the significant hazards and defects in the Recalled Digitek®. The Recalled Digitek® was unreasonably dangerous than would be reasonably contemplated by the ordinary user. During the period that were taking the Recalled Digitek®, the medication was being utilized in a manner that was intended by the Defendants. At the time Plaintiffs received and consumed the Recalled Digitek®, it was represented to be safe and free from latent defects and was to have an approved dose of digoxin consistent with the does set forth on the label.

134. At all relevant times, Defendants knew or should have known of the danger associated with the use of the Recalled Digitek®, as well as the defective nature of the Recalled Digitek®, but continued to manufacture, sell, distribute, label, package, market, promote, release and/or supply the Recalled Digitek® so as to maximize sales and profits at the expense of the public health and safety and to maintain the Digitek® brand integrtiy, in conscious disregard of the foreseeable harm caused by the Recalled Digitek®.

135. At all relevant times, the Recalled Digitek® was in a defective and unreasonably dangerous condition which would not be recognized or contemplated by a reasonable person among the expected users and consumers at the time it left the control of the Defendants.

136. At all relevant times, the Recalled Digitek® was defective and unreasonably dangerous when used in reasonably expectable ways of handling and/or consumption.

137. At all relevant times, the Recalled Digitek® was expected to reach, and did reach, the ultimate user or consumer without substantial change in the condition in which it was sold, supplied, manufactured, produced, and/or distributed by Defendants.

138. At all relevant times, the Recalled Digitek® was defective and unreasonably dangerous under section 402(A) *Restatement (Second) of Torts*, and the *New Jersey Products Liability Act*.

139. Defendants are strictly liable to Plaintiffs for manufacturing, producing and placing into the stream of commerce a product which was defective and unreasonably dangerous for its reasonably foreseeable uses at the time it left the control of Defendants.

140. As a direct and proximate result of Defendants' defective and unreasonably dangerous products, Plaintiffs were harmed as aforesaid.

COUNT 8
BREACH OF EXPRESS WARRANTY

141. Plaintiffs incorporate by reference each preceding and succeeding paragraphs as though set forth fully at length herein.

142. At all relevant times, Defendants warranted that the Recalled Digitek® was safe and not defective and/or unreasonably dangerous as stated above and warranted that it continued a dose of digoxin that consistent with the dose set forth on its label and was otherwise safe for human ingestion.

143. At all relevant times, Defendant placed the Recalled Digitek® into the stream of commerce for sale and recommended its use to physicians, the FDA and consumers without adequately warning physicians, the FDA and consumers, including the Plaintiffs, of the risks associated with the use of the Recalled Digitek® and that it contained an amount of digoxin different from the labeled dose and sometimes exceeding the approved dose for human ingestion.

144. At all relevant times, Defendants had a duty to exercise reasonable care in the

design, development, testing, manufacture, production, formulation, processing, compounding, labeling, packaging, inspections, supply, distribution, marketing, promotion, sale and release of the Recalled Digitek®, including a duty to:

a. Ensure that the product did not cause the user unreasonably dangerous side-effects;

b. Ensure that the product was labeled accurately;

c. Ensure that the amount, stregnth and dose of the digoxin in the product was consistent with the that set forth on the label and to ensure that the does was approved by the FDA as a dose safe for use in humans;

d. Warn of dangerous and potentially fatal side-effects; and,

e. Disclose adverse material facts when making representations to physicians, the FDA and the public at large, including Plaintiffs.

145. When the Physicians of the Plaintiffs prescribed the Recalled Digitek® and the Plaintiffs decided to use the Recalled Digitek®, both Plaintiffs, and their physicians reasonably relied upon the Defendants and their agents to disclose known defects, risks, dangers and side-effects of the Recalled Digitek® and whether the Recalled Digitek® contained an dose of digoxin, consistent with its label, and not in excess or below the dose approved for ingestion by humans.

146. Plaintiffs' physician(s), the FDA and/or Plaintiffs had no knowledge of the falsity or incompleteness of the Defendants' statements and representations concerning the Recalled Digitek® when Plaintiffs' physician(s) prescribed and/or otherwise provided Recalled Digitek® and Plaintiffs purchased and used the Recalled Digitek® as designed, developed, tested, manufactured, produced, dosed, inspected, labeled, packaged, distributed, supplied, marketed, promoted, sold and otherwise released into the stream of commerce by the Defendants. Plaintiffs

justifiably and detrimentally relied on the warranties and representations of Defendants in the purchase and use of the Recalled Digitek®.

147. At all relevant times, Defendants were under a duty to disclose the defective and unsafe nature of the Recalled Digitek® to physicians, the FDA, consumers and users, such as the Plaintiffs. Defendants had sole access to material facts concerning the defects, and Defendants knew that physicians, the FDA and users, such as Plaintiffs, could not have reasonably discovered such defects.

148. By the conduct alleged, Defendants, its agents and employees expressly warranted to Plaintiffs and their physicians(s) that the Recalled Digitek® was packaged and labeled accurately that it contained the approved dose of digoxin, that the drug was safe, merchantable and fit for the purpose intended.

149. This warranty was breached because the Recalled Digitek® was misbranded, adulterated and did not contain the amount of digoxin as stated in the label and sometimes the approved dose for ingestion by humans, nor was it safe and effective as Defendants represented, and Plaintiffs were harmed as aforesaid.

150. As a direct and proximate result of Defendants' defective and unreasonably dangerous Recalled Digitek® and their breach of express warranty, Plaintiffs were harmed as aforesaid.

COUNT 9
BREACH OF IMPLIED WARRANTY
(N.J.S.A. 2A:58C-1 *et seq.*)

151. Plaintiffs incorporate by reference each preceding and succeeding paragraphs as though set forth fully at length herein:

152. The Defendants designed, developed, manufactured, marketed, produced, tested, inspected, distributed, supplied, released and sold the Recalled Digitek® for the treatment of certain

cardiac heart problems.

153. At the time that the Defendants designed, developed, manufactured, marketed, produced, tested, inspected, distributed, supplied, released and sold the Recalled Digitek®, they knew of the use for which the subject product was intended and impliedly warranted it to be of merchantable quality and safe and fit for such use.

154. The Plaintiffs, individually and through their prescribing physician, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

155. The Plaintiffswere prescribed, purchased, and used the Recalled Digitek® for its intended purpose.

156. Due to the Defendants' wrongful conduct as alleged herein, the Plaintiffs could not have known about the mislabeling, misbranding, exceessive dose of digoxin, the nature of the risks and side-effects associated with the Recalled Digitek® until after they used it.

157. Contrary to the implied warranty for the subject product, the Recalled Digitek® was not of merchantable quality, and was not safe or fit for its intended uses and purposes, as alleged herein.

158. As a direct and proximate result of the acts and omissions of Defendants and the defective and unreasonably dangerous Recalled Digitek® and their breach of implied warranty, Plaintiffs were harmed as aforesaid, and Plaintiffs have suffered injuries and damages including death.

COUNT 10
MISREPRESENTATION AND SUPPRESSION BY DEFENDANTS

159. Plaintiffs incorporate by reference each preceding and succeeding paragraphs as though set forth fully at length herein:

160. Defendants misrepresented to Plaintiffs and the medical community the safety and

effectivenss of the Recalled Digitek® and/or fraudulently, intentionally and/or negligently concealed material information, including adverse information regarding the safety and effectiveness of the Recalled Digitek® and the dose of digoxin contained therein.

161. Defendants made misrepresentations and actively concealed adverse information at a time when the Defendants knew, or should have known, that the Recalled Digitek® had defects, dangers, and characteristics that were other than that what the Defendants had represented to Plaintiffs, the public, the FDA and the medical community generally. Specifically, Defendants misrepresented to and/or actively concealed from Plaintiffs, the FDA and, the medical community and consuming public that:

a. Some doses of digoxin in the Recalled Digitek® was not a dose that was approved by the FDA;

b. The dose of the digoxin in the Recalled Digitek® was not what the label represented the dose to be;

c. Some of doses of digoxin in the Recalled Digitek® exceeded the dose approved for use in humans;

d. The dose of digoxin in the Recalled Digitek® was unsafe, hazardous and dangerous; and,

e. Ingesting the Recalled Digitek® would result in an overdose or underdose.

162. The misrepresentations of and/or active concealment alleged were perpetuated directly and/or indirectly by Defendants.

163. Defendants knew or should have known that these representations were false and made the representations with the intent or purpose that Plaintiffs would rely on them, leading to the use of the Recalled Digitek®.

164. At the time of Defendants' fraudulent misrepresentations, Plaintiffs were uanware of the falsity of the statements being made and believed them to be true. Plaintiffs had no knowledge of the information concealed and/or suppressed by Defendants.

165. Plaintiffs justifiably relied on and/or were induced by the misrepresentations and/or active concealment and relied on the absence of safety information which the Defendants did suppress, conceal or failed to disclose to the detriment of the Plaintiffs.

166. Defendants had a duty to warn Plaintiffs, the public, the FDA and the medical community, about the misbranding, adulteration and potential risks and complications associated with the Recalled Digitek® in a timely manner but failed to do so.

167. The misrepresentations and active fraudulent concealment by the Defendants constitutes a continuing tort against the Plaintiffs who ingested the Recalled Digitek®.

168. Defendants made the misrepresentations and actively concealed information about the defects and dangers of the Recalled Digitek® with the intention and specific desire that the healthcare professionals treating the Plaintiffs, the Plaintiffs, and the consuming public would rely on such or the absence of information in selecting and using the Recalled Digitek® as a medical treatment.

169. As a direct and proximate result of the fraudulent acts and omissions, suppression and misrepresentation of Defendants, Plaintiffs may have suffered injuries and damages including death.

COUNT 11
FRAUD

170. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

171. Defendants fraudulently, intentionally, wilfully and wantonly, purposefully, knowingly, recklessly, negligently and/or in fact materially misrepresented both affirmatively and by omission that the Recalled Digitek® was of good quality, non-defective, safe for its intended use, merchantable, and fit for its particular purposes.

172. Defendants intended, knew, and/or should have known that Plaintiffs would be induced, by the aforesaid misrepresentations, to use the Recalled Digitek®.

173. In using the Recalled Digitek®, Plaintiffs justifiably relied on Defendants' representations that its Recalled Digitek® was of good quality, non-defective, labeled accurately, not adulterated and was safe for its intended use, merchantable, and fit for its particular purposes.

174. The Recalled Digitek® was, in fact, misbranded, adulterated, defective and unreasonably dangerous, as recited above.

175. As a direct and proximate result of the defective and unreasonably dangerous Recalled Digitek® as well as its affirmative misrepresentations and omissions, Plaintiffs were harmed as aforesaid.

COUNT 12
NEGLIGENT MISREPRESETANTION

176. Plaintiffs incorporate by reference each preceding and succeeding paragraphs as though set forth fully at length herein.

177. Defendants, in addition to knowing misrepresetnations, made misrepresentations without any reasonable grounds for believing their statements to be true to Plaintiffs, other patients, and the medical community.

178. Defendants, through its misrepesentations, intended to induce justifiable reliance by Plaintiffs, other patients, and the medical community.

179. Defendants, through its labeling, marketing compaign and communications with treating physicians, was in a relationship so close to that of Plaintiffs and other patients that it approaches and resembles privity.

180. Defendants owes a duty to the medical community, Plaintiffs and other consumers, to conduct appropriate and adequate inspections and tests for all of their products, including the

Recalled Digitek®, and to use safe and good manufacturing and production practices, to provide appropriate and adequate information and warnings but they failed to do so.

181. Defendants failed to conduct appropriate or adequate inspections, tests on the Recalled Digitek®.

182. As a direct and proximate result of Defendants' negligent misrepresentations the Plaintiffs were harmed as aforesaid.

COUNT 13
VIOLATIONS OF NEW JERSEY CONSUMER FRAUD ACT
(N.J.S.A. 56:8-1 *et seq.*)

183. Plaintiffs incorporate by reference each preceding and succeeding paragraphs as though set forth fully at length herein.

184. The Recalled Digitek® is considered "merchandise" as that term is defined by *N.J.S.A.* 56:8-1(c).

185. At all relevant times, Defendants knew or should have known that the use of the Recalled Digitek® caused serious and life-threatening injuries but failed to warn the public, including the Plaintiffs of the same.

186. At all relevant times, Defendants made untrue, deceptive or misleading representations of material facts to and omitted and/or concealed material facts from Plaintiffs, the FDA, the public and the medical community in the product packaging, labeling, advertising, direct-to-consumer advertising, promotional campaigns and other materials, among other ways, regarding the safety and amount of digoxin of the Recalled Digitek®. Moreover, Defendants downplayed and/or understated the serious nature of the risks associated with Recalled Digitek® in order to increase the sales of the Recalled Digitek® and maintain their share of the digoxin market and maintaining the integrity of the Digitek® brand.

187. At all relevant times, Defendants' statements and omissions were undertaken with

the intent that the FDA, physicians, and consumers, including the Plaintiffs would rely on the Defendants' statements and/or omissions.

188. Plaintiffs were prescribed and/or otherwise provided with, and consumed, the Recalled Digitek® and have or may have suffered ascertainable losses of money as a result of the Defendants' use or employment of the methods, acts or practices or failure to act, alleged herein.

189. The aforesaid misbranding, adulteration, supply, distribution and sale and release of the Recalled Digitek® into the stream of commerce constitutes an unconscionable commercial practice, deception, false pretense, misrepresentations, and/or the knowing concealment, suppression, or omission of material facts with the intent that others would rely upon such concealment, suppression or omission in connections with the sale or advertisement of such merchandise or services by Defendants.

190. At all relevant times, Defendants concealed, omitted, or minimized that the Recalled Digitek® had an amount of digoxin inconsistent with the stated dose on the label and sometimes exeeding the approved dose for use in humans or provided mis-information about adverse reactions, risks and potential harms from the Recalled Digitek® and succeeded in persuading consumers, including Plaintiffs to purchase and ingest the Recalled Digitek® despite the lack of safety and the risk of adverse medical reactions, including but not limited to those set forth in the Digitek® label.

191. At all relevant times, Defendants practice of promoting and marketing the Recalled Digitek® created and reinforced a false impression as to the safety of the Recalled Digitek®, thereby placing consumers, including Plaintiffs at risk of serious and potential lethal effects.

192. At all relevant times, the Recalled Digitek® lacked appropriate warnings and information about the dose of Digoxin, and the packaging and labels used by Defendants were misleading, inaccurate, incomplete and/or untimely.

193. Defendants violated their post-manufacture duty to warn which arose when it knew, or with reasonable care should have known, that the Recalled Digitek® was injurious and sometimes fatal.

194. At the time when consumers, including the Plaintiffs, purchased and ingested the Recalled Digitek®, Defendants intended that others would rely upon the concealment, suppression or omission of the risks of ingesting the Recalled Digitek®.

195. Defendants' actions in connection with design, development, manufacture, production, labeling, packaging, supplying, testing, inspecting, distributing, marketing, release and sale of the Recalled Digitek® as set forth herein evidence a lack of good-faith, honesty in fact and were not observant of fair dealing so as to constitute unconscionable commercial practices.

196. Defendants acted willfully, knowingly, intentionally, unconscionably and with reckless indifference when committing these acts of consumer fraud.

197. As a proximate result of the acts of consumer fraud set forth above, Plaintiffs purchased and ingested an unsafe, misbranded, adulterated, product and incurred monetary expense and the risk to themselves and members of their households that they would consume the Recalled Digitek® and thereby suffer an increased risk of harm as previously set forth herein.

198. The conduct of the Defendants, as set forth above, constitutes unfair, deceptive, unlawful, and/or unconscionable acts and/or practices prohibited under the *New Jersey Consumer Fraud Act*, N.J.S.A. 56:8-2, et seq. and the Consumer Protection Statutes of the various states.

199. As a direct and proximate result of Defendants' unfair, deceptive, unlawful, and/or unconscionable acts or practices in violation of the aforesaid Consumer Protection Laws.

COUNT 14
UNJUST ENRICHMENT

200. Plaintiffs incorporate by reference each preceding and succeeding paragraph as

though set forth fully at length herein.

201. Defendants accepted payment from Plaintiffs for the purchase of the Recalled Digitek®.

202. Plaintiffs did not receive a safe and effective drug for which they paid and as aforesaid, received a dangerous and defective drug.

203. It would be inequitable for Defendants to retain this money because Plaintiffs did not in fact receive a safe and effective drug.

COUNT 15
WRONGFUL DEATH

204. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

205. Plaintiffs brings this claim on behalf of herself and the Decedent's lawful beneficiaries and Plaintiff Decedent's daughter brings this claim on behalf of Decedent's lawful beneficiaries. The Decedent's lawful beneficiaries include the Decedent's beneficiaries.

206. As a result of the acts and/or omissions of the Defendants as set forth herein, Decedent suffered serious emotional and bodily injuries resulting in her death as stated above.

207. Plaintiffs (as Decedent's surviving relative) are entitled to recover damages as Decedent would have of her were living, as a result of the acts and/or omissions of the Defendants as specifically pled herein pursuant to *N.J.S.A.* 2A:15-3.

208. Plaintiffs are entitled to recover punitive damages and damages for the pain and suffering caused to Decedent from the acts and omissions of the Defendant as specifically pled herein, including, without limitation, punitive damages pursuant to *N.J.S.A.* 2A:15-3.

COUNT 16
SURVIVAL ACTION

209. Plaintiffs incorporate by reference each preceding and succeeding paragraph as

though set forth fully at length herein.

210. As a result fo the actions and inactions of the Defendant, Decedent was caused to suffer before her death.

211. Plaintiffs, on behalf of the Decedent's estate, seeks damages compensable under the Survival Act, *N.J.S.A.* 2A:14-5 (or any sucessor statute) against the defendant. Plaintiffs, in their own right, seek damages compensable under the Survival Act, *N.J.S.A.*:15-3 (or any successor statute) against the Defendants.

V. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants for damages including exemplary damages if applicable to which she is entitled by law, as well as all costs of this action, to the full extent of the law including:

1. judgment for Plaintiffs and against Defendants;
2. damages to compensate Plaintiffs for injuries sustained as a result of Digitek use, past and future lost of income proven at trial;
3. physical pain and suffering of the Plaintiffs; and any and all damages allowed under the wrongful death and survivor statutes and laws or other statutes and laws that apply, wrongfule death and survival damages;
4. pre and post judgment interest at the lawful rate;
5. reasonable attorneys' fees and costs and expert fees;
6. restitution of all purchase costs that Plaintiffs for Digitek disgorgement of Defendants' profits,
7. exemplary and punitive damages in an amount in excess of the jurisdictional limits, trebled on all applicable Counts;
8. all Bill of Costs elements;

9. a trial by jury on all issues of the case; and

10. for any other relief as this court may deem equitable and just.

VI. JURY TRIAL DEMANDED

Plaintiffs demand that all issues of fact of this case be tried to a properly impaneled jury.

BY: _____

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